UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION
CASE NO. 4:19-cv-00075

ISAM BASHIRI PLAINTIFF

v.

BIOMET ORTHOPEDICS, LLC

and

ZIMMER BIOMET HOLDINGS, INC.

and

BIOMET MANUFACTURING CORP.

and

BIOMET U.S. RECONSTRUCTION, LLC DEFENDANTS

COMPLAINT

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Plaintiff, Isam Bashiri, by and through the undersigned attorneys, for his complaint against Defendants, states as follows:

1. This is a product liability case involving a defective hip implant system. Plaintiff Isam Bashiri ("Plaintiff") had a Biomet Metal-on-Metal Hip System ("Hip System") implanted in his hip joint. The Hip System suffers from defects that cause excessive amounts of cobalt and chromium to corrode and wear from the surfaces of the acetabular cup, the femoral head, and the taper sleeve, which in turn causes the hip implant to fail and the surrounding tissue and bone to die, requiring a painful and costly surgery to extract the failed hip from the body.

2. As a result of these defects, Plaintiff's Hip System had an unreasonably high risk of failing in his body, causing failure of the device and/or toxic levels of cobalt and chromium, tissue and bone destruction, and the need for Plaintiff to undergo a complicated and risky surgery to remove and replace the defective implant.

PARTIES

3. Plaintiff Isam Bashiri is a citizen and resident of Plano, Texas, which is located in Collin County, Texas and is part of the Eastern District of Texas, U.S. District Court.

4. Defendant, Biomet Orthopedics, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw, Indiana. Biomet Orthopedics, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Orthopedics, LLC is a citizen of Indiana.

5. Defendant, Zimmer Biomet Holdings, Inc., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet, Inc. is a citizen of Indiana.

6. Defendant, Biomet Manufacturing Corp., is, and at all times relevant to this Complaint was, an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet Manufacturing Corp. is a citizen of Indiana.

7. Biomet U.S. Reconstruction, LLC, is, and at all times relevant to this Complaint was, an Indiana limited liability company, with its principal place of business in Warsaw, Indiana. Biomet U.S. Reconstruction, LLC is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant, Biomet, Inc., an Indiana corporation with its principal place of business in Warsaw, Indiana. Therefore, Biomet U.S. Reconstruction, LLC is a citizen of Indiana.

8. At all times mentioned, each Defendant was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Hip System that is the subject of this litigation. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

9. All Defendants are collectively referred to herein as "Biomet."

JURISDICTION AND VENUE

10. This is a civil action of which U.S. District Court for the Eastern District of Texas has original jurisdiction under 28 U.S.C. section 1332 because it is between citizens of different states (as described above) and the amount in controversy exceeds the sum or value of $75,000, exclusive of costs and interest. The cost of a typical hip revision surgery by itself often exceeds this threshold amount, before additional damages are calculated for pain and suffering, revision complications, lost wages, permanent physical impairment, and diminished quality of life.

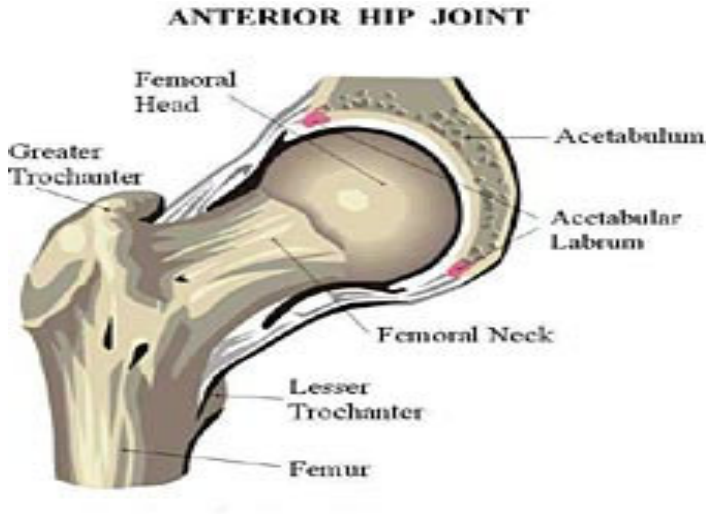
11. Venue is proper in the U.S. District Court for the Eastern District of Texas pursuant to 28 U.S.C. §1391 because it is the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred and all Defendants are subject to personal jurisdiction in that District.

FACTUAL BACKGROUND

A. The Hip System Is Defective and Was Not Adequately Tested

12. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a

cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.



13. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. The majority of total hip replacement systems consist of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

14. Typical hip replacement systems utilize a metal-plastic interface that has been refined to the point where a greater than 99.5 percent success rate may be achieved per year.

15. The Hip System used in Plaintiff's surgery, described in greater detail below, uses a metal replacement femoral head interfacing directly with the interior of a metal acetabular cup and does not contain a plastic liner. Accordingly, this type of hip system is referred to as a metal-on-metal (hereafter "MoM") hip replacement.

16. MoM hip systems, such as the hip system implanted in Plaintiff, suffer from design and/or manufacturing defects that cause loosening of the device and/or excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter.

17. These cobalt and chromium particles prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, elevated levels of cobalt and chromium in the blood, heavy metal poisoning, pseudotumors, tissue necrosis, osteolysis, muscle wasting, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

18. In the 1960s and early 1970s, the orthopedic device industry experimented with various MoM designs for hip implants. The perceived benefit of MoM was the idea that metal was stronger than plastic, would last longer, and wear less. Further, the strength of the metal would theoretically allow for designs that increased range of motion.

19. However, by the mid-1970s, MoM hip implants were completely abandoned because the implants resulted in a high percentage of patients with poor clinical outcomes, mostly as a result of heavy poisoning and adverse local tissue reactions caused by metal ions released from the MoM bearing surface. The industry then shifted in favor of utilizing polyethylene components, which remained the industry standard during all relevant times.

20. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual*, *clinical* risks associated with using MoM technology for hip implants.

21. Despite the early failure of metal-on-metal technology and despite the near complete lack of a *clinical* safety record due to the previous abandonment of the technology,

Defendants designed, developed, promoted and manufactured the M2a metal-on-metal Hip System, which utilizes a MoM bearing surface. Common names for this M2a system include the M2a Magnum, the M2a-38, and the M2a Taper.

22. The design of the Hip System was not sufficiently tested by Biomet, and it was never approved by the FDA as being safe or effective for its intended purpose.

23. Biomet chose to forgo clinical trials related to the risks of heavy metal poisoning prior to bringing its first metal-on-metal Hip System to market in 2001 despite receiving warnings from the medical and scientific community about risks of the same posed by the Hip System's MoM bearing surface during the design phase and was notified of the need conduct clinical testing related to the release of metal ion's as early as 1995.

24. Indeed, in 1995 a conference was held in California, and attended by "approximately 100 researchers[,] clinicians, and industry representatives" who "presented the *state of the art interpretation* of the metal on metal total hip replacement's past performance, and the clinical, tribologic, and biologic considerations of all metal bearings."[1] Among the published conclusions from the workshop were the following:

- "Clinical failure of the McKee-Farrar and other early metal on metal prostheses was a multifactorial process. In the older designs, the rate of failure in the first few years of clinical use was higher than that of metal on polyethylene total hip replacements." (p. S297).
- "It was agreed that, in cases of failure, the histologic appearance of the tissues from failed metal on metal components, differed from those around failed metal on polyethylene components, often on a gross level. With the latter [i.e. polyethylene], the capsule [the tissue around the hip implant ball and socket] was often hyperplastic, vilous, and orange or tan. Where there is excessive metal debris, the tissues may be stained gray or black." (S298).

[1] Amstutz, Harlan C., et al. "Metal on Metal Total Hip Replacement Workshop Consensus Document." *Clinical Orthopaedics and Related Research*, no. 329S, Aug. 1996, pp. S297-303 (emphasis added).

- "Preliminary data suggest that wear particles generated in vivo by metal on metal hip implants are smaller than the polyethylene particles generated by metal on polyethylene implants." (S302).
- "The surface area, number, size, shape, and material of wear particles all affect the macrophage response [i.e., the body's response to a foreign object] to wear particles, but the relative importance of these factors is disputed. Very small metal particles (less than 1/2 a micron in diameter) have been reported around metal on metal bearings, but the information about the size, shape, and number of metallic particles generated in vivo is limited." (S302).
- "There are important differences in the cellular effects of metal particles versus metal ions. ... The **majority of participants agreed that CoCr** [Cobalt Chromium – the material Biomet used to make its metal on metal implants] in both particulate and ionic form, (Cr, Co, and Ni) **has a toxic effect on cells** that is dose and cell type dependent. There was **agreement that metal particles have potential systemic effects**, due to their potential to corrode, but there was no consensus about the local effects." (S303) (emphasis added).

25. But the Amstutz article was not the only one published at that time. Dr. Jonathan Black, a noted expert in the field of biomaterials, published an article in the same edition of *Clinical Orthopaedics and Related Research* further highlighting the risks associated with metal-on-metal articulations.[2]

26. Dr. Black summarized his conclusion as follows:

> The question of whether metal on metal articulation is a practical alternative to current practice is essentially that of whether it is as safe as, and more effective than, metal on polymer articulations in use for more than 20 years. **Unfortunately, the metal on metal articulation introduces additional biologic risks associated with production of increased metallic corrosion and wear products**. .... Therefore, it is suggested that, consistent with modern technical and ethical standards, it cannot be concluded that metal on metal articulation is a practical alternative to current metal on polymer designs.[3]

27. The problems with metal-on-metal hips and the risks identified by Black and the workshop consensus document were not new; other studies had been published more than a decade

[2] Black, Jonathan "Metal on Metal Bearings: A Practical Alternative to Metal on Polyethylene Total Joints?" *Clinical Orthopaedics and Related Research*, no. 329S, Aug. 1996, pp. S244-55.

[3] *Id*. at S244. (emphasis added)

earlier. In 1986, surgeons from the Norfolk and Norwich Hospital in the United Kingdom reported on the performance of McKee-Farrar metal-on-metal hips implanted around the same time the Mayo Clinic was implanting Charnley hips.[4]

28. Whereas Mayo reported that more than 80% of the Charnley hips were still in use after 20 years, August found that only 27% of the McKee-Farrar metal-on-metal hips survived that long.[5]

29. In 1981, Dr. Rae at Cambridge University examined the toxicity of various metals used in orthopedic implants. Dr. Rae reached the following conclusions regarding heavy metal toxicity:

> It appears, therefore, that potentially the most harmful components are cobalt from cobalt-chromium alloy, nickel from stainless steel, and vanadium from titanium alloy. As far as can be estimated, the only combination of materials which is likely to give rise to toxic levels of metal under clinical conditions, is cobalt-chromium alloy articulating against itself to produce relatively high levels of cobalt.[6]

30. Other leading surgeons and researchers studied the levels of cobalt and chromium in patients with metal-on-metal hip implants, and reported their findings in 1996.[7]

31. Their findings clearly showed an association between metal-on-metal implants and elevated metal ion levels in blood serum and urine. Specifically, they reported on eight patients with McKee-Farrar metal-on-metal hips implanted for more than 20 years who had serum chromium levels nine times greater than the control group; urine chromium levels 35 times greater than the control group; and serum cobalt levels three times higher than the control group. In

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[4] August, A. C., et al. "The McKee-Farrar Hip Arthroplasty: A Long-Term Study." *Journal of Bone and Joint Surgery (UK)*, vol. 68-B, no. 4, Aug. 1986, pp. 520-27.

[5] *Id*. at p. 525.

[6] Rae, T. "The Toxicity of Metals Used in Orthopaedic Prostheses." *Journal of Bone and Joint Surgery (UK)*, vol. 63-B, no. 3, 1981, p. 435.

[7] Jacobs, Joshua J. "Cobalt and Chromium Concentrations in Patients With Metal on Metal Total Hip Replacements." *Clinical Orthopaedics and Related Research*, no. 329S, Aug. 1996, pp. S256-63.

addition, significantly elevated serum and urine cobalt and chromium levels were found in patients who had metal-on-metal hips implanted for less than two years. [8]

32. Defendants thus knew or should have known, based on the documented failures of previous MoM hip systems, that the safety and efficacy of the Hip Systems' predicate devices did not adequately support the safety or efficacy of the Hip System. Defendants also had warning about the dangers of MoM hip systems based on similar problems with other MoM devices as early as 2004, including the DePuy ASR, the DePuy Pinnacle, the Zimmer Durom, the Wright Conserve, and the Smith & Nephew Birmingham. These dangerous MoM hip systems resulted in a cascade of lawsuits — more than 25,000 complaints filed in federal courts across the U.S. since 2008. Biomet alone faced approximately 3,000 of these federal lawsuits, although most of them have settled.[9]

33. Despite the weight of scientific authority warning of the clinical risks associated with MoM hip replacement systems, the only system for which Biomet performed any pre-approval clinical testing was the M2a-Taper; however, that study was insufficient because it lacked an adequate sample size and Biomet did not follow the patients for a long enough period of time. Biomet also did not gather data about the harmful risks of metal ions as part of the study. Biomet began selling the M2a-38 and M2a-Magnum systems, which were derived from the M2a Taper device, without testing them in people. Biomet also failed to adequately study the characteristics and potential hazards of the wear debris particles generated by its MoM devices.

34. Rather than conduct a comprehensive clinical trial to evaluate the clinical performance of MoM hips, or the clinical significance and potential hazards associated with metal

[8] *Id.* at p. 256

[9] See, e.g., Biomet Settlement Agreement, 2014, available at https://www.innd.uscourts.gov/sites/innd/files/Biomet%20Settlement%20Agreement.pdf (describing $200,000 value for each metal-on-metal hip failure).

wear debris and ions generated with normal use of the devices, Biomet chose to market its M2a MoM hip implants to surgeons and patients as being safe and longer lasting than metal-on-polyethylene implants, especially for younger and more active patients.

35. Biomet utilized the FDA's "510(k)" procedures to gain "clearance" to sell the Hip System in the United States.

36. The "510(k)" process does not equate to "approval" for sale based on any analysis of clinical safety or efficacy, nor is this process designed to do so. In fact, the FDA's own regulations prohibit device manufacturers from suggesting that 510(k) clearance denotes FDA approval:

> Submission of a premarket notification in accordance with this subpart, and a subsequent determination by the Commissioner that the device intended for introduction into commercial distribution is substantially equivalent to a device in commercial distribution before May 28, 1976…does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.

21 C.F.R. § 807.97.

37. Instead, the 510(k) process is a way to bring a product to the market based on an intended seller's representation that a product is "substantially equivalent" to products that were either previously cleared for sale through the same process or were grandfathered in before regulations requiring the pre-market testing of medical devices were adopted in 1976.

38. The 510(k) process does not, however, prohibit the submission of clinical data regarding the safety and efficacy of product as part of the clearance process.

39. The FDA's "clearance" for the Hip System to be sold did not involve any extensive scrutiny for clinical safety and efficacy before sale and instead included only a showing of substantial equivalence to previously cleared devices by Biomet.

40. Thus, Biomet deliberately chose not to obtain and submit clinical data along with its pre-market notification as a part of the 510(k) process for the M2a Hip Systems.

41. During the same time that Biomet was developing its M2a metal-on-metal hip implant system, Biomet and other manufacturers were also evaluating ways of improving the wear characteristics of polyethylene implants. Older model polyethylene implants, over a significant period of time (typically more than 10 years) could lead to a condition known as osteolysis. By 2000, surgeons were well aware of osteolysis, how to diagnose it, and how to treat it. But also by 2000, Biomet and other hip implant manufacturers had developed manufacturing techniques that improved the wear characteristics of polyethylene such that the reported wear rates were, by the manufacturers' own admissions, so low that they would not lead to osteolysis.

42. Despite these advances in polyethylene wear characteristics, Biomet chose to promote its M2a metal-on-metal hip implants beginning in 2001 despite having failed to adequately assess the safety of those devices or the risks associated with their use. Metal-on-metal total hip replacement devices are no longer sold in the United States; instead, surgeons routinely implant metal-on-polyethylene devices that are essentially unchanged since the early 2000s.

43. The M2a MoM Hip Systems designed, manufactured, and sold by Biomet produce an exponentially larger number of smaller and more toxic wear particles in comparison to hip replacement systems utilizing a polyethylene liner.

44. Conversely, plastic wear particles released from polyethylene implants are much larger, less numerous, and less reactive than the heavy metal wear particles released by the M2a Hip System. Testing protocols for wear in hip implants systems utilizing polyethylene liners thus allow for measurements of the plastic wear particles by total weight.

45. These same protocols, however, explicitly warn against their use for measuring

metal wear in MoM hip systems like the M2a. This is, in large part, because the toxicity and reactivity of heavy metal wear particles is not related to total weight, but particle size and count.

46. Biomet had actual knowledge by 2000 that heavy metal poisoning is related to the size and total number of these metal particles produced by the M2a MoM Hip System as opposed to the total weight of said particles. Further, Biomet had actual knowledge that these particles were toxic.

47. Biomet thus knowingly and intentionally conducted laboratory "wear testing" for the M2a in a way that was *only* designed for testing hip implants that utilized polyethylene liners. Particularly, these test protocols only measured wear by total weight.

48. Despite the fact that Biomet failed to conduct comprehensive clinical testing of its metal-on-metal Hip System, including but not limited to the potential for release of metal ions from the bearing surface, and misused laboratory "wear testing" protocols designed for use in polyethylene hip systems, it has claimed that the Hip System offers extremely low wear rates compared to other hip replacements systems, and is safer than other MoM hip prostheses. Biomet even went so far as to claim that the implants had "clinically proven results" immediately upon marketing.[10]

49. In fact, in a 2004 publication titled "Metal Ions – A Scientific Review," Biomet falsely concludes that: "Extensive research and years of clinical trials have failed to prove any cause for concern associated with the ion levels exhibited from metal-on-metal implants."[11]

[10] *See* *http://www.biomet.com/wps/wcm/connect/internet/acb6d5c6-e3e9-42e2-b3e6-83fd38a567f1/Y-BMT-735_021502_K.pdf?MOD=AJPERES*, (Last accessed December 19, 2018).
[11] *See* http://www.grossortho.com/images/stories/pdf/currenttopics/MetalIonWhitePaper.pdf (Last viewed Dec. 28, 2018).

50. In a heading on page 7 of the publication, Biomet went so far as to claim that: "Cobalt and Chromium may be beneficial to the body as established by research and listed by the US government."[12]

B. Biomet Sold the Hip Implant To Plaintiff After It Knew It Was Defective, That It Had Injured Others, And That It Could Injure Plaintiff.

51. It was not long after Biomet launched the Hip System that reports of failures began flooding into Biomet. For example, in August 2004, Biomet received a complaint that a patient had to undergo a surgery to remove and replace an M2a-Magnum Hip System because it had failed after only 3 years. Biomet subsequently closed its investigation of this complaint.

52. Biomet would go on to receive hundreds of similar complaints reporting that the Hip System had failed, and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed MOM components.

53. Biomet, due to their sales representatives' role in the sale of particular implant components to orthopedic surgeons, has notice of every surgery in which Biomet components are implanted. This includes surgeries in which Biomet components are used to replace failed M2a implants. As a result, Biomet possesses a unique set of clinical information through which the success or failure of their implants can be analyzed. However, Biomet failed to report many of these hip failures, and took steps to mask the true failure rate of its MoM hip systems, which approaches a 20 percent revision rate at ten years for certain systems, four times higher than the generally accepted benchmark safety rate of just 5 percent at ten years.

54. Biomet was also made aware of failures of the Hip System through interactions and communications with customer surgeons. Biomet did not take proper action in response to these

[12] *Id.*

interactions and communications, including but not limited to reporting relative adverse event reports to the FDA.

55. Instead, Biomet intentionally suppressed its rate of "adverse events reported to the FDA" with regards to the Hip System and failed to properly analyze clinical information in its possession regarding implants which it sells by knowingly underreporting complaints and revision surgeries about the Hip System to the FDA in an intentional scheme to mislead the public, the orthopedic community, and Plaintiff about the safety and efficacy of the Hip System. Biomet further based its claims regarding the adverse event rate of the Hip System based on the underreported adverse event rates of the Hip System's predicate devices.

56. Biomet accomplished this, at least in part, by a pattern and practice of only reporting revision surgeries as adverse events to the FDA if patients who underwent a revision surgery *also* filed a lawsuit.

57. At all times relevant to this lawsuit, Biomet was aware that its pattern and practice of making the reporting of adverse events contingent upon whether the patient also filed a lawsuit relating to the adverse event would result in an unreasonable underreporting of adverse events across the patient population implanted with the Hip System as a whole.

58. In furtherance of its scheme to mislead the medical community regarding the dangers posed by the M2a Hip System, Biomet explicitly trained its sales representatives on how to deceptively convince surgeons that reports of heavy metal poisoning are all fake; merely a theoretical concern; and a scheme by competitors who do not sell MoM hip replacements to steal business.

59. In 2016 and 2018 this practice resulted in multiple "483" observations by the FDA regarding Biomet's failure to properly handle complaint reports and failure to properly analyze

clinical information regarding product failures.

60. As numerous failures the of Hip System were reported to Biomet, it continued to actively promote, market and defend its defective product. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants. These brochures were given to doctors around the world to encourage them to use the Hip System.

61. To date, more than 350 reports of adverse events associated with the Hip System have been filed with the FDA. By the time Biomet sold the Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the Hip System and other related MoM hip products. Consequently, Biomet was fully aware that some of its Hip Systems were defective and that dozens of patients already had been injured by that defect. Based on this information, Biomet should have recalled the Hip System before it was sold to Plaintiff. At minimum, Biomet should have stopped selling the Hip System when it became aware that it had catastrophically failed in several patients.

62. Despite knowing or being in a position where they should have known, of the unreasonable risks associated with the Hip System, Biomet continued to market and sell the Hip System throughout the United States. Biomet failed to provide adequate warnings to the public or the medical community regarding the risks associated with the Hip System. Rather, Biomet continued to falsely claim to the medical community and the public the Hip System was safe.

63. Upon information and belief, further false statements by Biomet regarding the Hip System include, but are not limited to, the following:

a. Biomet falsely claimed that the Hip System was a safe and effective hip replacement system.
b. Biomet falsely claimed that the Hip System was clinically safe and effective based on laboratory tests.
c. Biomet falsely claimed that the Hip System was clinically safe and effective based on clinical tests.

d. Biomet falsely attributed data regarding clinical failures of the Hip System to improper patient selection by surgeons.

e. Biomet falsely attributed data regarding clinical failures of the Hip System to improper surgical technique by surgeons.

f. Biomet falsely attributed data regarding clinical failures of the Hip System to patient characteristics.

g. Biomet falsely claimed the clinical existence of a run-in period for the Hip System.

h. Biomet falsely claimed that the metal wear clinically produced by the Hip System during the theoretical run-in period was within safe limits.

i. Biomet falsely claimed that metal wear clinically released from the Hip System is reduced after a theoretical run-in period of three years.

j. Biomet falsely presented clinical research data from within the theoretical run-in period as being indicative of the long-term clinical safety and efficacy of the Hip System.

k. Biomet falsely claimed knowledge of clinically safe limits for metal wear.

l. Biomet falsely attributed metal wear production to surgical technique and environmental contaminants to the exclusion of device related factors.

m. Biomet falsely attributed clinical reactions to metal wear to patient hyper-sensitivity.

n. Biomet falsely claimed the Hip System was highly wear-resistant.

o. Biomet falsely claimed the Hip System exhibits less metal wear than other competing types of hip implants.

p. Biomet falsely claimed they could not draw conclusions regarding the safety or efficacy of the Hip System even after analyzing reports of revisions and explanted components.

q. Biomet falsely claimed that the design differences between the Hip System and other MoM hips made the Hip System safer and more effective than other MoM hips.

r. Biomet falsely claimed that the design differences between the Hip System and other MoM hips made the Hip System a clinically safe and effective hip replacement system.

64. In addition to falsely claiming that the Hip system was safe, Biomet omitted a great deal of material information regarding the safety and efficacy of the Hip System to Plaintiff, Plaintiff's surgeon, and the orthopedic community including, but not limited to:

a. The lack of evidence to support the clinical existence of fluid film lubrication during a large percentage of normal, everyday use of the Hip System;

b. The clinical existence of greater histological reaction to the comparatively smaller

wear particles produced by the Hip System as compared to the larger particles produced by Metal of Polyethylene ("MoP") hips that were available at the same time.

c. The likelihood of a smaller volume of metal particles from the Hip System producing greater negative clinical effects than a larger volume of plastic particles from other MoP hips available at the same time;

d. A large number of Hip System failures were assumed to not be device-related despite a lack of adequate investigation;

e. Hip System design characteristics were a known potential cause of the complaints and revisions being reported;

f. Long-term clinical studies of the Hip System were purposefully avoided or omitted when promoting the long-term outcome of the Hip System;

g. "Hypersensitivity" to the Hip System and/or metal ions released by the same is defined solely by the occurrence of a negative outcome and not by a pre-disposition for a negative outcome;

h. Citations to data regarding the purported long-term success of past generations of MoM hips focused solely on the percentage of those devices not revised after a certain period of time, omitting data regarding those that failed and required revision;

i. Though metal ions can be excreted through the urine, the excretion cannot be enough to offset the amount of metal ions and wear being released into the body;

65. At the same time that Biomet was reassuring Orthopedic surgeons and the public of the safety of the M2a Hip Systems, they were receiving reports of just the opposite from healthcare providers and governments across the world.

66. Isala Kliniekin ("Isala"), a hospital located in Zwolle, The Netherlands, implanted patients with Biomet's M2a Magnum MoM hip replacements from 2005 to 2007.

67. In 2010, Isala reported to Biomet that when it performed CT scans of over 100 patient's hips, more than a third had pseudotumors adjacent to their M2a Magnum hip implants.

68. Isala further reported to Biomet that the necessity for revision surgery was not identified until Isala conducted screening protocols of their M2a patients.

69. Isala warned that by the time that swelling pain, and clicking indicating tissue death resulting from the heavy metal poisoning became apparent, the patient may have already suffered

extensive injury.

70. In 2010, Isala informed Biomet that it had ceased implanting Biomet M2a hip replacements in its patients.

71. Isala encouraged Biomet to adopt the advanced screening protocol of all patients with Biomet M2a products implants in their bodies and warned that without such, patients may be a risk without knowing it.

72. Isala subsequently reported some of its findings regarding the M2a Magnum in a British Medical Journal.[13]

73. Likewise, Turku University in Turku, Finland implanted the Biomet M2a Magnum Hip System into patients at its university hospital from 2005 to 2012.

74. In 2013, Turku University reported to Biomet that when the University examined a sample of their patients implanted with the M2a Magnum, over half of the patients were experiencing ARMD or "Adverse Reaction to Metal Debris" from the M2a Magnum.

75. MRIs of the sample of Turku University M2a Magnum patients revealed that over half had a pseudotumor or fluid collection in their hip.

76. Despite having a long and close relationship with Biomet, Turku University stated in a 2013 publication of the Nordic Orthopedic Federation that "ARMD is common after… Magnum total hip arthroplasty, and we discourage the use of this device."[14]

77. Despite the critical warning published by Isala and Turku University regarding the negative outcomes experienced by their M2a patients, and the need for surgeons to screen their own patients for ARMD, Biomet instead continued to promote the M2a Hip Systems for

[13] Bosker B, Ettema H, Boomsma M, et al. High incidence of pseudotumor formation after large-diameter metal-on-metal total hip replacement: a prospective cohort study. J Bone Joint Surg Br. 2012 Jun;94(6):755-6 I.
[14] Mokka J, Junnila M, Seppanen M, et al. Adverse reaction to metal debris after ReCap-MAGNUM-Magnum large diameter-head metal-on-metal total hip arthroplasty. Acta Orthopaedica. 2013;84(6):549-554.

implantation into the bodies of patients.

78. Similar to the warning it received from Isala and Turku University, Biomet was notified of the dangers posed by the M2a Hip Systems from government authorities in Australia and Great Britain.

79. Australia has a world-leading implant registry which keeps track of every orthopedic hip replacement sold, implanted, and replaced in Australia.

80. Biomet ceased Australian sales of the M2a Hip Systems in 2011.

81. In 2014, the Australian government informed Biomet that is was seeing excessive failure rates of M2a Hip Systems in Australian patients.

82. In 2015, The Australian government issued a "Hazard Alert" recalling the Biomet M2a Hip Systems due to a "higher than expected revision rate."

83. Because Biomet had already ceased selling the M2a in Australia in 2011, the "Hazard Alert" consisted of a mandate that Biomet notify implanting surgeons of the recall and excessive revision rates of the M2a Hip Systems.

84. Biomet failed to disclose to orthopedic surgeons or the public in the United States that it ceased selling the M2a in Australia in 2011, while continuing to these same hip systems in the United States until 2015.

85. Similar to Australia, the National Joint Registry (hereinafter "NJR") of England, Wales, and Northern Ireland gathers information on orthopedic implants sold in those countries.

86. Biomet ceased selling M2a Hip Systems in Europe in 2012.

87. On April 12, 2016, Biomet issued a "Field Safety Corrective Action" in various European nations, including England, Wales, and Northern Ireland, for the M2a 38 Hip System.

88. Biomet admitted to European surgeons in this safety alert that registry data revealed

the M2a 38 to have a "higher than expected revision rate."

89. Biomet failed to disclose to orthopedic surgeons or the public in the United States that the ceased selling the M2a Hip Systems in Europe in 2012, while continuing to sell the same devices in the United States until 2015.

90. As a result of Biomet Defendants' efforts to fraudulently conceal and distort information related to the safety record for the Hip System, the orthopedic community and Plaintiff's surgeon, in particular, did not and could not have knowledge or sophistication equal to the Biomet Defendants with regards to the risks of the Hip System. Because metal-on-metal hip systems typically do not generate harmful levels of metal ions until many years after implantation, and because Biomet failed to recall the systems, Plaintiff could not have known of the potential legal claim related to Plaintiff's failed hip until, at the very least, the date of Plaintiff's revision surgery. Plaintiff's claim is therefore well within the applicable statute of limitations.

91. Biomet's reason to conceal the defect in its Hip System is clear. Hip implant sales are critically important to Biomet. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors. The company ultimately was purchased by a private equity firm in 2007 for $10 billion. More recently, in April 2014, managers at Biomet announced yet another sale, this time to competitor Zimmer Holdings, Inc., in a deal valued at $13.35 billion. Throughout this time period, Biomet was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell its various MoM Hip Systems despite the fact that it knew these products were defective.

C. Plaintiff's Hip System Components Were Defective.

92. On or about November 20, 2007, Plaintiff underwent left hip replacement surgery by Michael Taba, M.D. at Baylor Regional Medical Center at Plano in Plano, Texas, during which a Biomet M2a Magnum metal-on-metal prostheses, was implanted in his left hip joint. By this time, reports of adverse events associated with the M2a Magnum, M2a-38, M2a-Taper and other Biomet devices had been filed with the FDA and Biomet knew that the product was subject to failure due to excessive metal-on-metal wear and other factors. But Biomet refused to disclose that information to Plaintiff, his physicians, or the public. Instead, Biomet circulated promotional literature to medical providers and the general public stating that the health consequences of heavy metals such as cobalt and chromium were unknown, even though Biomet knew this was not true. For example, Biomet suggested that chromium and/or cobalt are safe because they are sometimes included in multivitamins in trace amounts. Further, instead of acknowledging that chromium and cobalt are dangerous in patients' bodies, Biomet blamed patients, particularly women, for being "hypersensitive" to certain metals. In other cases, Biomet blamed surgeons for metal-on-metal failure, claiming they didn't implant the devices at exactly the right angle.

93. Biomet misrepresented to Plaintiff and his orthopedic surgeon that the Hip System was safe and effective. In reliance on these representations and omissions, Plaintiff's orthopedic surgeon made the decision to use the Hip System. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the Biomet Hip System.

94. As a result of the defective design, manufacture and composition of the Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant caused him severe pain and he was forced to undergo costly and painful revision surgery on December 13, 2017, on the left side, by John Appleton, M.D. at Baylor Medical Center at Uptown in Dallas,

Texas. During the surgery, Dr. Appleton observed metallosis and a fluid collection around Plaintiff's hip.

95. Having to go through a revision surgery has subjected Plaintiff to much greater risks of future complications than he had before the revision surgery.

96. Several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. In other words, hip replacement patients who have undergone a revision surgery are almost ***four times more likely*** to suffer from a hip dislocation than those who have not. (Phillips CB, *et al*., Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *American Journal of Bone and Joint Surgery* 2003; 85:20–26.)

97. As a direct and proximate result of the failure of his defective Hip Systems and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed $75,000 jurisdictional minimum of this court.

COUNT I
(Strict Product Liability)

98. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

99. Biomet designed, manufactured, promoted, distributed, marketed, and sold the Hip System.

100. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff and his physician, without substantial change in the condition in which it was sold.

101. At all times material hereto, the Hip System that was designed, manufactured, promoted, distributed, marketed, and sold by Biomet was in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce. Such condition included, but is not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, the Hip System contained manufacturing defects, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

b. When placed in the stream of commerce, the Hip System contained unreasonably dangerous design defects and was not reasonably safe for the intended use, subjecting Plaintiff and others to risks, including the risk that the acetabular component would not properly grow into the bone, causing the hip system to prematurely fail and requiring a complex, risky, and painful surgery to remove and replace the defective product;

c. The Hip System was insufficiently tested; and

d. The Hip System was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff and his physicians of the full nature or extent of the risks associated with its use.

102. The manufacturing and/or design defects present in the Hip System when it was placed into the stream of commerce by Biomet include, but are not limited to, the following:

a. The design of the Hip System caused its bearing surface to generate excessive cobalt and chromium metal debris into the body as compared to other hip replacement products on the market;

b. The surface roughness of the M2a was not within acceptable standards and specifications;

c. The thickness, porosity, tensile strength of the plasma porous spray coating was not within acceptable standards and/or specifications;

d. The plasma porous spray coating utilized was not designed to be utilized on acetabular cup of the M2a;

e. The plasma porous spray coating contributed to generating excessive metal wear debris;

f. The design of the acetabular cup caused it to fail to obtain bone ingrowth;

g. The claimed advantages of the M2a did not justify the additional risks created by metal debris of the M2a as compared non-MoM hip replacements on the market at the time of Plaintiff's index surgery;

h. The design of the instrumentation, including the inserter tools, resulted in excessive failure;

i. The design of the M2a caused the adapter and stem to cold weld;

103. Biomet knew or should have known of the dangers associated with the use of the Hip System, as well as the defective nature of the Hip System. Despite this knowledge, Biomet continued to manufacture, sell, distribute, promote and supply the Hip System so as to maximize sales and profits at the expense of the public health and safety. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

104. Plaintiff and his surgeon used the M2a-Magnum Hip Systems as directed for its intended purpose.

105. At all times herein mentioned, the Hip System was defective, and Biomet knew that it was to be used by the user without inspection for defects therein. Moreover, at the time of the use of the subject products, neither Plaintiff nor his physician knew or had reason to know of the existence of the aforementioned defects. Neither Plaintiff nor his physicians could have discovered the defects in the Hip System through the exercise of reasonable care.

106. The Hip System had not been materially altered or modified prior to its implantation in Plaintiff.

107. As a direct and proximate result of the failure of the defective Hip System, Plaintiff suffered the injuries and damages as described herein.

COUNT II
(Negligence)

108. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

109. At all times herein, mentioned Biomet had a duty to exercise reasonable care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System to ensure that it would be safely used in a manner and for a purpose for which it was made.

110. Biomet, maliciously, recklessly and/or negligently failed to exercise ordinary care in the design, manufacture, testing, inspection, labeling, promotion, marketing, and sale of the Hip System.

111. Biomet, maliciously, recklessly and/or negligently made misrepresentations and/or omission about the safety and effectiveness of the Hip System to Plaintiff and his orthopedic surgeon. In reliance on these misrepresentations and/or omission, Plaintiff's orthopedic surgeon decided to use the Hip Implant in Plaintiff's surgery. If it was not for the misrepresentations and/or

omissions by Biomet, Plaintiff's orthopedic surgeon would not have used the Hip System in Plaintiff's surgery.

112. Biomet maliciously, recklessly and/or negligently failed in their duty to exercise reasonable care in the provision of an adequate warning to Plaintiff and his physicians as to the risks of the Hip System.

113. Biomet maliciously, recklessly and/or negligently failed to exercise reasonable care in the post-marketing warnings as to the risks of the Hip System when they knew or should have known of said risks.

114. Biomet's conduct was done in conscious disregard of the foreseeable harm caused by the Hip System and in conscious disregard for the rights and safety of consumers such as Plaintiff.

115. As a result of Biomet's wrongful conduct, Plaintiff suffered injuries and damages as alleged herein.

COUNT III
(Breach of Implied Warranties)

116. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

117. Prior to the time that the Hip System was used by Plaintiff, Biomet impliedly warranted to Plaintiff and his physicians that the Hip System was of merchantable quality and safe and fit for the use for which it was intended.

118. Plaintiff's physicians were and are unskilled in the research, design and manufacture of the Hip System, and they reasonably relied entirely on the skill, judgment and implied warranty of Biomet in using the Hip System.

119. The Hip System was neither safe for its intended use nor of merchantable quality, as warranted by Biomet, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user.

120. Biomet, by selling, delivering and/or distributing the defective Hip System to Plaintiff, breached the implied warranty of merchantability and fitness and caused Plaintiff pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

121. As a result of the aforementioned breach of implied warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT IV
(Breach of Express Warranty)

122. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

123. At all times herein mentioned, Biomet expressly warranted to Plaintiff and his physicians, by and through statements made by Biomet or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the aforementioned Hip System was safe, effective, fit and proper for its intended use.

124. In utilizing the aforementioned Hip System, Plaintiff and his physician relied on the skill, judgment, representations and foregoing express warranties of Biomet.

125. Said warranties and representations were false in that the aforementioned Hip System was not safe and was unfit for the uses for which it was intended.

126. As a result of the foregoing breach of express warranties by Biomet, Plaintiff suffered injuries and damages as alleged herein.

COUNT V

(Violation of The Texas Deceptive Trade Practices-Consumer Protection Act)

127. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further allege as follows:

128. Defendants are liable to the Plaintiff pursuant to the Texas Deceptive Trade Practices-Consumer Protection Act, Tex. Bus. & Com. Code §17.41 *et. seq*. As a direct and proximate result of Defendant's wrongful acts and omissions, Plaintiff has sustained and will continue to sustain damages consisting of: past and future lost wages, medical, permanency and incidental expenses, according to proof; past and future general damages for pain and suffering, according to proof.

129. In the course of the transactions that are the subject of this lawsuit, Defendant engaged in the following unfair and deceptive acts, methods or practices:

a. Causing a probability of confusion or misunderstanding about the source, sponsorship, approval, or certification of its services;

b. Representing that its services have sponsorship, approval, characteristics, and benefits that they do not have;

c. Representing that its services were of workmanlike quality when, in fact they were not;

d. Causing a probability of confusion or of misunderstanding concerning Plaintiff's legal rights, obligations, or remedies;

e. Failing to reveal material facts, the omission of which tended to mislead or deceive Plaintiff, and which could not reasonably be known by the Plaintiff;

f. Taking or arranging for the consumer to sign an acknowledgment, certificate, or other writing affirming acceptance, delivery, compliance with a requirement of law,

or other performance, when Defendant knew or had reason to know that the statement was not true;

g. Entering into a consumer transaction in which Plaintiff purportedly waived a right, benefit, or immunity provided by law, without conspicuous disclosure and without Plaintiff's specific consent;

h. Failing to provide promised benefits, including benefits arising by operation of law;

i. Failing to reveal facts that are material to the transaction in light of representations of fact made in a positive manner; and

j. Such other and further acts or omissions as may be determined through further investigation and discovery.

130. Upon information and belief, the violations described above were not the result of bona fide error, in that Defendant did not have procedures in place designed to prevent injury to Plaintiff from their defective product, the defectiveness of which the Defendant had reason to know and Defendant has engaged in similar misconduct in connection with sales of other defective hip replacement implants.

131. As a result of the Defendant's actions described above, Plaintiff has suffered a loss within the meaning of the Act and is also entitled to statutory damages and attorney fees as provided in the Act.

132. Plaintiff did not become aware of the connection and/or nexus between his injuries and the above-described negligent design of the Biomet Hip System until his first revision surgery.

COUNT VI
(Punitive Damages)

133. Plaintiff incorporates by reference as if fully set forth verbatim each and every

allegation in the Complaint.

134. The acts, representations, conduct, and omissions of Biomet, as alleged throughout this Complaint were malicious, willful, wanton, intentional, oppressive, and fraudulent. Biomet committed these acts with a conscious disregard for the rights of Plaintiff and other M2a Hip System users for the primary purpose of increasing its own profits from the sale and distribution of the M2a Hip Systems. Biomet's outrageous and unconscionable conduct warrants an award of exemplary and punitive damages in an amount appropriate to punish and deter such conduct of Biomet in the future.

135. Prior to the manufacturing, sale, and distribution of the M2a Hip Systems, Biomet knew that MoM hip systems like the M2a products posed a grave risk of injury to the public based on the weight of available scientific knowledge, including but not limited to long term clinical data comparing first generation MoM hip systems to MoP hip systems.

136. Despite their knowledge of the clinical risks posed by the MoM hip systems prior to the release of the M2a Hip Systems for sale to the public, Biomet deliberately chose to forgo any clinical studies regarding the long-term risks posed by the release of metal ions into the body. Biomet instead willfully and wantonly chose to deceive the medical community and the public by claiming that the M2a was safe and effective based upon wear studies using parameters that it knew were *only* approved for measuring polyethylene wear despite the fact that no M2a products utilized polyethylene components. Biomet also claimed in its promotional literature that its MoM hip systems would last 600 years, effectively guaranteeing that they would never need to be replaced during a patient's lifetime.

137. Despite knowledge of the risk of premature failure of MoM hip systems, Biomet, acting through its officers, directors, and managing agents, for the purpose of enhancing its profits,

knowingly and deliberately failed to remedy the known defects in the M2a Hip Systems and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in the M2a system even as the M2a-38 reached a reported failure rate of nearly twenty percent at ten years. This rate is approximately four times higher than the benchmark revision rate for a hip system to be considered safe and effective.

138. Indeed, as similar products including the DePuy ASR, DePuy Pinnacle, Zimmer Durom, Wright Conserve, and Smith & Nephew Birmingham Hip Resurfacing were recalled or withdrawn from the market in the wake of thousands of failure reports and associated lawsuits, Biomet chose not to issue a recall of the M2a Hip Systems in a wanton disregard for the safety of Plaintiff and the public at large. In fact, as these reports were pouring in during the period from 2008 to 2010, Biomet doubled down on its MoM hip systems, organizing a "Re-Launch" of the Magnum system, supported by promotional literature, posters, marketing brochures, and public relations kits.[15]

139. Biomet likewise exercised grossly negligent practices in manufacturing and packaging the Hip Systems, in violation of the "good manufacturing requirements" as required by the FDA. This course of conduct led to the issuance of a warning from the FDA to Biomet in 2018 as a result of its failure to cure deficiencies in its manufacturing practices observed as part of a 2016 audit of its Warsaw, Indiana, manufacturing facilities. Biomet's failure to maintain adequate manufacturing conditions and practices for the Hip System and subsequent failure to correct the same created a safety risk to the purchasers of its various products including the Hip Systems.[16]

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[15] See, e.g., *The Truth About Metal on Metal*, July 2009; *Talking Points About Metal-on-Metal Implants*, March 2010; *ASR System User Conversion Leads to Big Business*, July 2010.

[16] *See* Joseph Matrisciano, *Warning Letter to Zimmer Biomet*, Aug. 24, 2018, available at https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm618429.htm (Last viewed Dec. 27, 2018).

140. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of the M2a Hip Systems, knowing these actions would expose users to serious danger. In order to advance Biomet's pecuniary interest and monetary profits, Biomet made claims that the dangers of MoM hip systems were unknown, or that they were the fault of patients and surgeons, even as evidence to the contrary continued to pile up year after year. Biomet failed to recall the M2a hip systems in the United States, even though they were recalled years earlier in Australia and other jurisdictions.[17]

141. Biomet's conduct, as described above, risked the lives of consumer and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

PRAYER FOR RELIEF

THEREFORE, Plaintiff demands judgment for the following:

1. Past and future lost wages, medical, permanency and incidental expenses, according to proof;
2. Past and future general damages for pain and suffering, according to proof;
3. Punitive and exemplary damages in an amount to be determined at trial;
4. Prejudgment and post judgment interest;
5. Costs to bring this action; and
6. Such other and further relief as the court may deem just and proper.

[17] See ICIJ, *Medical Devices Harm Patients Worldwide as Governments Fail on Safety*, Nov. 25, 2018, available at https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/ ("A metal-on-metal hip manufactured by Indiana-based Biomet has been linked to flesh-rotting metallosis, and the company discontinued sales of the device several years ago. Biomet later sent safety alerts to surgeons and other health care providers in Australia, the U.K. and a slew of other Western European countries in 2015 and 2016, but not to those in Canada and the U.S. Had the FDA pushed for a recall of the Biomet hip device in the U.S., the company could have been forced to send such letters to American doctors.")

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, the Plaintiffs demand trial by jury in this action of all issues so triable.

Respectfully submitted,

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